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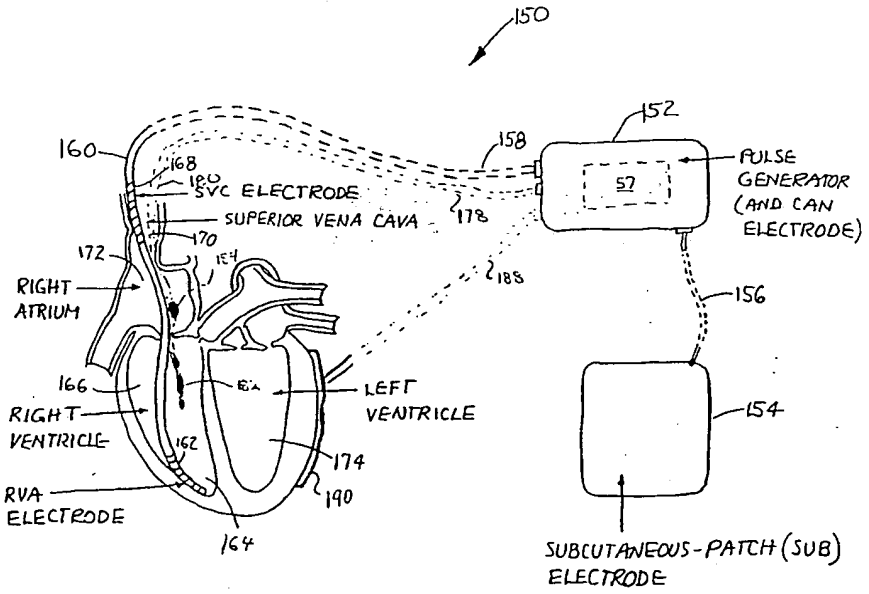
(57) Abstract

An implantable apparatus for treating ventricular tachycardia, and a method for operating the same, delivers a series of anti-tachycardia stimulation pulses, each of which has energy values of less than 5 joules, and at least one of which is a far-field pulse that is a short, relatively high-voltage pulse delivered through at least two far-field electrodes. The series of anti-tachycardia stimulation pulses are preferably delivered by an implantable cardioverter defibrillator (ICD) having at least two relatively larger-surface-area defibrillation-style far-field electrodes having a relatively large inter-electrode distance, and, optionally, a pair of smaller-surface-area pacing-style electrodes having a relatively smaller inter-electrode distance. Each series of anti-tachycardia stimulation pulses is delivered as a committed burst of pulses without any intervening monitoring, and with one or more bursts being delivered by the ICD in response to the sensing of a ventricular tachycardia. By using the large surface area defibrillation-style electrodes to deliver at least one of the anti-tachycardia pulses, a far-field stimulation of the myocardium is induced in an effort to simultaneously extinguish the ventricular tachycardia throughout the myocardium.



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SYSTEM FOR TREATMENT OF VENTRICULAR TACHYCARDIA USING A FAR-FIELD PULSE SERIES

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention pertains to systems used to treat human heart arrythmia conditions. More particularly, the present invention relates to an implantable apparatus for treating ventricular tachycardia and a method for operating such an apparatus.

2. Description of the Background Art

Ventricular tachycardia is a racing of the electrical signals within one or more regions of the ventricular chambers of the myocardium, i.e., the heart. Currently, the most accepted explanation for ventricular tachycardia is that a race condition is somehow started in a closed loop of myocardium with a diameter on the order of 1 cm, as illustrated in Figure 1. In this closed loop, the path of electrical cell stimulation is essentially circular, with a path length (circumference) sufficient to permit a given cell to repolarize, or to recover, from the previous stimulation, before the wave of cell stimulation comes around the circle the next time. In this way, the electrical cell stimulation within the closed loop is self sustaining and races ahead of the normal electrical cell stimulation of the myocardium.

In biomedical terminology, such a closed loop is described as a re-

entrant loop, terminology which generically identifies a situation where a path of adjacent-cell stimulation closes on itself, or reenters a previous path. In the loop case, the activated cells continue to activate cells in a circular rotation in continuous fashion. Immediately behind the cells just stimulated are cells that are fairly refractory or resistant to stimulation having not fully recovered from activation. Farther behind them are cells that are fully recovered (repolarized), and hence, are amenable to stimulation or reactivation.

This kind of single-source ventricular tachycardia as shown in Figure 1 generates a rather consistently shaped electrical signal, and hence, is referred to as a monomorphic ventricular tachycardia. If there is more than one source or more than one re-entrant loop involved in the tachycardia, then the arrhythmia is referred to as a polymorphic ventricular tachycardia.

Presently, the most common and accepted method for treating ventricular tachycardia with an implantable cardioverter defibrillator (ICD) is to deliver a series of pacing pulses at a location of the heart remote to the re-entrant loop. This series of tachycardia pacing pulses is selected to have a rate that is slightly higher than the rate of the ventricular tachycardia, and each pulse has an energy of less than about 50 microjoules. The tachycardia pacing pulses are delivered through conventional pacing electrodes that are essentially small point sources. The choice of using small point sources to deliver the tachycardia pacing pulses is made because the energy required to stimulate the closest neighboring cells is smaller. The activation pulse wave then spreads through the myocardium towards the re-entrant loop. In theory, one of the tachycardia pacing pulses should arrive at the re-entrant loop in the correct phase and thereby stimulate the cells of the re-entrant loop that have recovered fully from activation. If this happens, then these cells will be refractory to continued loop activation, and hence, the ventricular tachycardia will terminate.

The basic concept of anti-tachycardia pacing was invented by

Zacouto in the late 1960s. There have been many patents on traditional anti-tachycardia pacing. Examples are: U.S. Patent No. 4,312,356 to Sowton; U.S. Patent No. 4,390,021 to Spurrell; U.S. Patent No. 4,398,536 to Nappholz; U.S. Patent No. 4,408,606 to Spurrell; U.S. Patent No. 4,488,554 to Nappholz; and U.S. Patent No. 4,577,633 to Berkovitz.

Some of the early anti-tachycardia pacing devices were similar to conventional pacemakers and had no ability to deliver conventional defibrillation countershock in addition to the anti-tachycardia pacing pulses. Due to an occasional iatrogenic deterioration of the ventricular tachycardia, such as an acceleration of the tachycardia that requires a defibrillation countershock, anti-tachycardia pacing therapy is currently only delivered by ICD systems which incorporate the anti-tachycardia pacing as a programmable option for the ICD.

The most typical treatment modalities for anti-tachycardia pacing have used a burst of ten pacing pulses delivered at a rate slightly higher than the ventricular-tachycardia rate. The choice of a higher rate of pacing is made because the anti-tachycardia pacing pulses will vary in phase with respect to the ventricular tachycardia, and thus, there is an increased opportunity for the pacing wave to arrive at a depolarized portion of the re-entrant loop before the pacing wave is itself annihilated. In an effort to improve the effectiveness of anti-tachycardia pacing, pulse-rate scanning is sometimes employed in an effort to hit the correct rate. In scanning, the pacing value is increased with every burst. In another technique designed to improve the effectiveness of anti-tachycardia pacing, the pacing rate is sometimes increased or ramped during the anti-tachycardia pacing burst.

There are several timing problems that prevent a 100% success rate with existing anti-tachycardia pacing techniques. The major problem is that the treatment pulse wave must arrive at the nearest side of the re-entrant loop while it is in repolarization, or amenable to activation. Before it can do this, the treatment wave must progress through myocardium without being blocked by the activation waves emanating from the loop itself. Such blocking can happen because the re-entrant loop

is generating an expanding activation wave throughout the myocardium in a fashion similar to the waves from a pebble dropped into the center of a smooth pond. This problem is illustrated in Figure 2 which shows the treatment wave at the lower left emanating from a pacing electrode in this example. In an intermediate region, the treatment wave competes with the wave launched by the re-entrant loop responsible for the tachycardia, and has a fair probability of being blocked.

Primarily because of these critical timing constraints, anti-tachycardia pacing techniques have been reported to work only 50% to 90% of the time in cases of monomorphic ventricular tachycardia. Unfortunately, the series of anti-tachycardia pacing pulses sometimes not only fail to completely treat the arrythmia, but also may cause a higher-rate monomorphic ventricular tachycardia, or pulse-rate acceleration. This can result in patient unconsciousness, which requires a painful higher-energy defibrillation shock in order to terminate the arrythmia. Added to these problems for the monomorphic case, is the fact that for cases of polymorphic ventricular tachycardia with multiple loops (or sources), the prior art anti-tachycardia pacing therapy has essentially no chance of working.

The existing situation with respect to anti-tachycardia pacing treatment can be summarized as follows. The high pulse rate in monomorphic tachycardia is a consequence of an electrical cell stimulation signal circulating in a small-diameter closed loop at some location on the myocardium. The anti-tachycardia pacing therapy delivers a short series of pacing pulses at a rate higher than that of the tachycardia. The intent of the higher rate pacing therapy is to have the arrival of each wave coincide with the repolarized (or stimulation-amenable) zone present at the nearest edge to have a fair probability of success by arriving at just the right instant. The point of using a burst of pulses, rather than a long series, is to provide a quiet interval after therapy during which dominance can be reestablished by waves coming from the proper pacemaker (whether from the heart's natural pacing center, or

from the electrodes of a prosthetic pacemaker). The problem is that anti-tachycardia pacing often yields indifferent results, even in the simplest monomorphic case. The pacing pulse waves may not arrive at the right time, may be annihilated by tachycardia waves, and may induce even more serious arrythmia conditions.

In addition to the standard anti-tachycardia pacing treatment that uses pacing electrodes on a standard cardiac catheter to deliver tachycardia pacing pulses, there is another accepted technique for treating ventricular tachycardias. This treatment, known as cardioversion, involves the delivery of a single electrical pulse to the entire myocardium through relatively large-area defibrillation electrodes. Such a cardioversion pulse usually has an energy in the neighborhood of 1-5 joules. This value is well above that of a anti-tachycardia pacing pulse, which is typically about 50 microjoules, but below that of a typical defibrillation pulse, which is typically greater than 5 joules. In essence, the cardioversion treatment is somewhat analogous to lighting a back-fire in the entire heart to stop a forest fire.

The existing technique for cardioversion is to use an ICD to deliver a single electrical pulse to the myocardium that it essentially the same as existing defibrillation pulses, only of a smaller initial voltage. In other words, the cardioversion pulse has the same shape and duration as existing defibrillation pulses, only an initial voltage of about 150 volts is used, rather than a typical initial voltage of between 600-750 volts for a defibrillation countershock. Because the objective of existing cardioversion treatment is to immerse all, or substantially all of the myocardium, in an electric field similar to, but less intense than, a defibrillation pulse, the single cardioversion pulse is delivered through defibrillation electrodes that have a larger surface area than pacemaker electrodes. Once the single cardioversion pulse is delivered, the ICD waits a couple of seconds for the heart to "recover" and then returns to a sensing mode to determine if the arrhythmia condition still exists. If the cardioversion pulse was unsuccessful in returning the heart to normal

cardiac rates, a standard treatment is to immediately deliver a defibrillation countershock pulse to recover normal heart activity.

While the idea of starting such a small backfire to extinguish ventricular tachycardia has success in some situations, existing clinical data suggests that cardioversion is successful in only about 50-70% of ventricular tachyarrhythmia conditions. In addition to being a very painful therapy, cardioversion can produce a deterioration of the tachycardia as often as 25% of the time the therapy is used. Finally, cardioversion is a relatively energy inefficient therapy compared to anti-tachycardia pacing in terms of the energy storage requirements necessary to deliver this type of pulse, particularly if several tachycardia incidents are treated in a short period of time.

Presently, the accepted practice is to deliver only one stimulation pulse at a time through the defibrillation electrodes, regardless of whether that stimulation pulse is a cardioversion pulse or a defibrillation countershock. The inventors are aware of only two prior attempts to deliver more than one electrical pulse at a time through the defibrillation electrodes.

In an abstract presented at the American Heart Association meeting in 1991, Shenasa reported applying a series of very low voltages, under one volt, to defibrillation electrodes. *Circ.* Vol. 84, No. 4, p. II-426 (Oct. 1991). He characterized these voltage as "sub-threshold stimulation" levels, and applied them at extremely high rates (50-millisecond pulses at the rate of 1200/minute). Shenasa's philosophy was to numb the myocardial cells near the electrodes in order to make these cells less likely to sustain the re-entrant loop of the ventricular tachycardia. He reported only a 52% success rate in treating tachycardia arrhythmias using this methodology.

U.S. Patent No. 4,996,984 to Sweeney discloses the use of a pair (or more) of pulses for defibrillation. The disclosure of this patent addresses only fibrillation arrythmia conditions, and not tachycardia arrhythmias. The stimulation pulses described have just slightly less energy than conventional defibrillation pulses, on the order of 10 joules, and

defibrillation voltage levels, on the order of about 600-750 volts. The use of a train of defibrillation pulses by Sweeny was apparently inspired by the 20-year-old work of the Swedish researcher Kugelberg, who also used trains of high-energy pulses to achieve defibrillation.

While existing anti-tachycardia therapies offer some hope for successful treatment of tachycardia arrhythmias without resorting to defibrillation, the problem with the existing therapies is that they are effective in only about 50% of the cases, and in as many as 25% of the cases, the anti-tachycardia therapy may actually cause deterioration of the arrhythmia into a condition that requires defibrillation. Accordingly, it would be desirable to provide an anti-tachycardia therapy that has a higher success rate and a lower complication rate than existing anti-tachycardia pacing and cardioversion therapies.

SUMMARY OF THE INVENTION

The present invention is an implantable apparatus for treating ventricular tachycardia, and a method for operating the same to deliver a series of anti-tachycardia stimulation pulses, each of which has energy values of less than 5 joules, and at least one of which is a far-field pulse. As defined by the present invention, a far-field pulse is a short, relatively high-voltage pulse delivered through at least two far-field electrodes. The series of anti-tachycardia stimulation pulses are preferably delivered by an implantable cardioverter defibrillator (ICD) having at least two relatively larger-surface-area defibrillation-style far-field electrodes having a relatively large inter-electrode distance, and, optionally, a pair of smaller-surface-area pacing-style electrodes having a relatively smaller inter-electrode distance. Each series of anti-tachycardia stimulation pulses is delivered as a committed burst of pulses without any intervening monitoring, and with one or more bursts being delivered by the ICD in response to the sensing of a ventricular tachycardia. By using the large surface area defibrillation-style electrodes to deliver at least one of the anti-tachycardia pulses, the present invention induces a far-field stimulation of

the myocardium in an effort to control and extinguish the ventricular tachycardia.

A typical far-field pulse of the present invention has an amplitude of between about 5 to 200 volts, an electrical energy between about 0.01 and 5 joules and a pulse duration of less than about 3 milliseconds. The voltage is chosen to be high enough to stimulate a large portion, but not necessarily all, of the myocardium directly, without consuming high levels of energy. The pulse duration is chosen to approximate the chronaxie time for far-field stimulation of depolarized heart cells. This approximate match minimizes the delivered energy required per pulse. The timing of the rate of delivery of the far-field pulses of the present invention is similar to the timing used in existing anti-tachycardia pacing. The entire burst of the series of stimulation pulses is delivered in less than about 5 seconds and is a committed sequence of stimulation pulses in the sense that no intervening monitoring of cardiac function is performed between stimulation pulses.

According to a first aspect of the invention, a method for operating an implantable device connected to at least two implanted electrodes located in a human patient to treat ventricular tachycardia, the method comprising the device-implemented steps of: (a) sensing a ventricular tachycardia in the human patient; and(b) in response to the ventricular tachycardia, delivering a series of two or more anti-tachycardia electrical stimulation pulses each having an energy value of less than about 5 joules to the two or more electrodes in a committed burst of less than about 5 seconds, at least one of the stimulation pulses being a far-field pulse having an energy value between about 0.01 joule and 5 joules, an amplitude between about 5 volts and 200 volts, and being delivered through two or more far-field electrodes having a combined surface area that exceeds about 1 square centimeter and an inter-electrode distance of greater than about 2 centimeters.

According to a second aspect of the invention, an implantable apparatus for treating ventricular tachycardia in a human patient,

comprises: two or more implanted electrodes, including at least a pair of far-field electrodes having a combined surface area that exceeds about 1 square centimeter and an inter-electrode distance of greater than about 2 centimeters; means for sensing a ventricular tachycardia in the human patient; and means for delivering a series of two or more anti-tachycardia electrical stimulation pulses in response to the ventricular tachycardia, each stimulation pulse having an energy value of less than about 5 joules to the two or more electrodes in a committed burst of less than about 5 seconds, at least one of the stimulation pulses being a far-field pulse delivered through the far-field electrodes and having an energy value between about 0.01 joule and 5 joules and an amplitude between about 5 volts and 200 volts.

It is important for an appreciation of this invention, to understand the difference between existing anti-tachycardia pacing and cardioversion techniques, and the far-field stimulation technique of the present invention.

In anti-tachycardia pacing stimulation, a low-voltage pulse of less than about 5-10 V is delivered into a pacing-style electrode, typically having an electrode surface area of much less than 1 cm^2 and an inter-electrode distance of less than about 2 centimeters. This pulse "breaks down", or renders conductive, the membranes of a handful of neighboring cells adjacent the pacing style electrodes so that they are activated (depolarized). These cells then stimulate more cells with which they are in direct contact. This cell-to-cell stimulation is not perfectly understood, but is thought to involve both ionic currents and capacitive coupling (displacement currents). The activation wave that is created by this point source cell-to-cell stimulation then moves through the heart at a velocity of about 100 cm/sec. An analogy is the lighting of a horizontal sheet of paper by igniting one corner. The corner is easy to ignite and the flame then spreads as an activation wave through the paper.

In cardioversion stimulation, a single moderately-high voltage pulse of about 150 V is delivered into a defibrillation-style electrode,

typically having a surface area of greater than about 1 cm^2 and an inter-electrode distance of greater than about 2 centimeters. The single cardioversion pulse has the same shape and duration as existing defibrillation pulses. Unlike the anti-tachycardia pacing pulses, the objective of existing cardioversion treatment is to immerse all, or substantially all of the myocardium, in an electric field similar to, but smaller than, a defibrillation pulse.

In the present invention, a far-field pulse series is used to treat the ventricular tachycardia. Unlike existing anti-tachycardia pacing treatments, the present invention delivers at least one far-field pulse in the series that is a relatively larger pulse routed through the defibrillation-type far-field electrodes. As will be described, the far-field electric field created by delivering the far-field pulse through at least two far-field electrodes having a relatively larger surface area and a relatively longer inter-electrode distance generates an electric field that simultaneously covers a larger portion of the myocardium and then quickly repeats this process at a rate faster than the rate of the ventricular tachycardia contractions. Unlike existing cardioversion treatments, the present invention delivers a committed series of pulses without any intervening monitoring, and not just a single pulse.

In essence, the theory behind the far-field pulse series is substantially different than the theories for either of the existing tachycardia treatments. Instead of trying to extinguish the ventricular tachycardia using a backfire-like wave of small stimulation pulses delivered from a pair of relatively close point source electrodes, or completely dousing the myocardium with a single smaller fibrillation-like pulse delivered from a pair of relatively distant large-area electrodes and then waiting for the normal stimulation of the heart to be reestablished. the present invention uses a series of stimulation pulses, at least one of which is a far-field pulse, to essentially simultaneously extinguish any re-entrant loops causing the ventricular tachycardia and also assist the heart in reestablishing normal sinus rhythm.

Thus, in the far-field stimulation of the present invention, the myocardial cells are simultaneously activated. This has a major advantage for dealing with monomorphic ventricular tachycardia, in that it removes (or at least minimizes) the timing problems of conventional anti-tachycardia pacing. This is because the far-field stimulation spreads not by activation of cells, but by electromagnetic wave propagation moving at a large fraction of the speed of light. This constitutes simultaneous stimulation as far as biological systems are concerned. More importantly, the far-field stimulation is not dependent on finding a path through inactivated (depolarized) cells. The desired stimulation spreads through electrical conduction, and not through cell-to-cell activation, which requires a path of cells that were not previously activated.

Hence, the far-field stimulation of the present invention does not suffer from the two timing problems that seriously limit the effectiveness of prior art anti-tachycardia pacing. First, it is not annihilated by activation waves emanating from the loop; and second, it need not first make contact with the re-entrant loop at a depolarized section. Also, unlike the single pulse techniques of the prior art cardioversion therapies, the present invention uses a committed series of anti-tachycardia stimulation pulses without any intervening monitoring or waiting periods in order to optimize the chances of destructively interfering with the re-entrant loop of the ventricular tachycardia so as to extinguish the arrhythmia.

It is important to note that the far-field stimulation need not be so strong as to stimulate the whole heart. If the strength of the pulses is sufficient to stimulate directly a relatively large portion of the functional myocardial tissue, then there is a significantly increased chance of terminating the ventricular tachycardia. Preferably, the stimulated region will be at least 50% of the functional myocardial tissue. If the generating loop is within the stimulated region, then the tachycardia may be terminated due to the electrical conduction of the far-field pulses within that region. If the loop is outside of this region, then the far-field stimulation still has a much improved chance of termination since there

are more and broader pathways for delivering the stimulation to the loop via cell-to-cell stimulation from the region which was stimulated by the far-field pulses.

There are many ways to deliver the far-field stimulation pulses to the larger surface area electrodes in accordance with the present invention. One technique is to use the main (defibrillation) capacitor in the implantable cardioverter defibrillator (ICD), charging it up to a relatively high voltage (5 to 200 volts) and delivering a short (about 1 millisecond) pulse from that capacitor. The advantage of this approach is that no additional capacitors are needed.

Another technique would be to use a separate smaller capacitor to deliver the far-field stimulation pulses. The advantage of this approach is that the additional capacitor may be charged to a lower voltage than that of the main capacitor. This would allow the main capacitor to be charged to a full voltage as a backup measure in case the far-field stimulation deteriorated the tachycardia condition. This additional capacitor value may also be chosen to deliver pulses of more energy efficiency to the heart. For example, the additional capacitor could have a value of some 15 to 20 microfarads, which is a small value compared to those of typical defibrillation capacitors of 140 to 180 microfarads.

Several alternate embodiments of the anti-tachycardia pulse trains used by the present invention exist. In each of them, the one-capacitor or the novel two-capacitor apparatus may be used to deliver the desired pulses.

In the preferred embodiment described above, all of the stimulation pulses in the series of committed pulses for each burst are far-field pulses. Preferably a series of 8-10 far-field pulses each of about 1 Joule and 150 V are delivered to the far-field electrodes at a rate of one every 250-350 milliseconds. After the first burst, the ICD can then monitor to determine if the far-field therapy was successful. If the initial therapy was not successful, then depending upon the sensed heart rate and programmable settings within the ICD, the ICD can deliver a subsequent far-field pulse

series of three bursts, for example, or can deliver a defibrillation countershock in the event that further anti-tachycardia therapy is no longer warranted.

In the first of the alternate embodiments, a relatively high-voltage anti-tachycardia far-field stimulation pulse is delivered to the far-field electrodes, with the interval between it and the last preceding contraction pulse from the tachycardial malfunction being shorter than the intervals between the train of tachycardia pulses. The far-field pulse is then followed by a train of ten or fewer pacing pulses delivered to pacing electrodes of a cardiac catheter, with the interval between the first of these and the far-field pulse, as well as their mutual intervals being at least as short as the first specified interval.

The next alternate embodiment of the present invention employs two relatively high-voltage far-field pulses in place of one. The interval between the two far-field pulses is the same as the first-specified interval in the previous embodiment, and the subsequent intervals of the pacing pulses are specified the same as those in the previous embodiment.

The last alternate embodiment is like the one just described, except that the interval between the two high-voltage far-field pulses is different from the intervals of the pacing pulses that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates the re-entrant loop of cells that enters into a widely accepted theory of ventricular tachycardia;

Figure 2 illustrates the interaction and annihilation of a wave from a conventional antitachycardia pacing pulse by a wave from the re-entrant loop;

Figure 3 illustrates the far-field stimulation of a preferred embodiment of the present invention for tachycardia termination;

Figure 4 illustrates schematically a circuit used for generating both defibrillation pulses and the antitachycardia stimulation pulses of a preferred embodiment of the present invention;

Figure 5 illustrates schematically a circuit of a preferred embodiment of the present invention used for generating defibrillation pulses with one capacitor and the anti-tachycardia stimulation pulses with an additional capacitor optimized for the purpose;

Figure 6 illustrates the placement and configuration of alternative embodiments of the electrodes of a preferred embodiment of the present invention; and

Figure 7 illustrates schematically a circuit used to produce the stimulation pulse series in an embodiment of the present invention that utilizes both far-field electrodes and pacing electrodes.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The following detailed description, when considered in connection with the accompanying drawings in which like reference numerals designate like parts throughout the figures, describes some of the embodiments of the present invention.

Figure 1 illustrates a re-entrant loop 10 of cells of the myocardium that enters into a widely accepted theory of ventricular tachycardia, the loop including in sequence activated cells 12, refractory cells 14 that have not yet recovered from activation, and depolarized cells 16 that can again be activated. It will be appreciated that a generally accepted definition of ventricular tachycardia is ventricular tachycardia contractions at a sustained rate of between 150 and 240 bpm.

Figure 2 illustrates schematically the geometrical pattern 20 of the interaction of a re-entrant loop 22 having a wave such as 24 interacting with a wave such as 26 that is emanating from the pacing electrodes of a conventional catheter in the conventional antitachycardia pacing therapy, with wave annihilation occurring in the region 28. For the reasons discussed above, the chances that the anti-tachy pacing wave 26 will succeed in blocking the re-entrant loop wave 24 is only about 50-80%.

Figure 3 illustrates schematically the geometrical pattern 30 of the stimulation of a re-entrant loop 32 with a wave 34 emanating from it, by

an electric field represented by lines of force such as 36, said electric field produced by far-field electrodes 38 and 40 in accordance with the present invention, and being relatively unaffected by the wave 34.

In far-field stimulation, an electric field of about 5 V/cm is generated within a region of the heart by each of the far-field pulses of the present invention. The cylindrical heart cells (myocytes) are about 25 μm in diameter and 75 μm in length. The cells have a membrane with a thickness of about 8 nm. The electric field of 5 V/cm is generated parallel to the axis of the cell. The voltage drop along the length of the cell is:

$$V_d = (5\ V/cm)\ (75\ \mu m) = 37.5\ mV \qquad \text{Eq. 0}$$

Intuitively, this does not seem like enough voltage to break down a cell membrane that swings by +/- 100 mV during depolarization. However, the insulating nature of the membrane, coupled with its conductive interior serves to concentrate this voltage drop through the membrane. Before membrane breakdown and cell activation, the internal cell potentials will be homogeneous. In other words, the membranes at each end of the cell must withstand the full voltage drop applied to the whole cell. Thus, each membrane end will see:

$$(37.5\ mV / 2) = 18.75\ mV \qquad \text{Eq. 1}$$

for a field of:

$$E = (18.75\ mV / 8\ nm) = 2{,}340\ kV/m \qquad \text{Eq. 2}$$

which is a sufficient field to break down the membrane and begin the cell-activation process.

The present invention also takes advantage of a subtle effect that can double this field. Instead of maintaining an isopotential cytoplasm (cell interior), the cell will try to minimize the internal field by redistributing charge. Another way of looking at this is that positive ions (mostly sodium) are attracted by the field toward the negatively charged electrode (cathode). This then increases the field across the membrane at the end where the positive sodium ions accumulate. A similar effect occurs with the negative chlorine ions at the opposite end.

It has further been found that the far-field pulses are more

effectively used by the myocardium when the pulse durations are shorter than the typical pulse durations used for existing defibrillation countershocks. Presently, the pulse durations of both cardioversion and defibrillation countershock pulse is at least about 7 ms. For optimal energy utilization, however, the far-field pulse should have a duration of less than about 5 ms and, depending upon whether the ICD is optimized for stored energy or for delivered energy, the ICD should have an optimum pulse duration of between about 0.8 ms and 1.2 ms (optimizing delivered energy) or between about 4.5 and 4.8 ms (optimizing stored energy).

Figure 4 illustrates schematically a circuit 41 used for generating both defibrillation pulses and the antitachycardia pulses of the present invention, including a high-voltage circuitry 42 that charges capacitor 44 when switch 46 is closed; when switch 46 is subsequently opened, the capacitor 44 is isolated and can then be discharged by closing switch 48, thus delivering an energetic defibrillation pulse to cardiac electrodes 50 and 52. In a similar way, the capacitor 44 can be charged to a lower voltage and then discharged to deliver one or more lower-energy cardioversion pulses to the heart, or two or more antitachycardia pacing pulses of the present invention to the heart.

Figure 5 illustrates schematically a circuit 60 of the present invention used for generating both defibrillation pulses and the anti-tachycardia stimulation pulses of the present invention, including high-voltage circuitry 42 that charges defibrillation capacitor 44 when switch 46 is closed; when switch 46 is subsequently opened, the capacitor 44 is isolated and can then be discharged by closing switch 48, thus delivering an energetic defibrillation pulse to cardiac electrodes 50 and 52. In a similar way, the smaller anti-tachycardia capacitor 62 can be charged to a lower voltage by closing switch 64 and then discharged after opening switch 64 by closing switch 66 to deliver an optimized lower-energy cardioversion far-field pulse to the heart, a process that can be repeated to deliver two or more such far-field pulses, or to deliver two or more

optimized anti-tachycardia pacing pulses of the present invention to the heart as part of a committed series of pulses.

It will be appreciated that in Figure 4, the switch 46 is closed to charge the capacitor 44 for delivery of a conventional defibrillation pulse. In Figure 5, on the other hand, switch 46 is opened to isolate the defibrillation capacitor 44, and then the switch 48 is closed to deliver the defibrillation pulse to the heart. The smaller and additional anti-tachycardia capacitor 62, on the other hand, is charged by closing switch 64. After that, switch 64 is opened to isolate capacitor 62, and then switch 66 is closed to deliver an antitachycardia pulse to the same electrodes as before.

Figure 6 illustrates schematically and for purposes of illustration a defibrillation system 150 including a subcutaneously implanted ICD or pulse generator 157 optionally serving as a CAN electrode 152. In the embodiment shown in Figure 6, the pulse generator 157 is attached to a subcutaneously implanted SUB electrode 154 by interconnection lead 156, by interconnection lead 158 to a cardiac defibrillation-style catheter 160, by interconnection lead 178 to a cardiac pacing-style catheter 180, and by interconnection lead 188 to an epicardial patch electrode 190. The defibrillation-style catheter 160 includes a first endocardial-coil electrode 162 positioned at the apex 164 of the right ventricle 166, the coil being the RVA electrode 162, and a second endocardial-coil electrode 168 positioned in the superior vena cava 170, which is above the right atrium 172, the second coil being the SVC electrode 168. The pacing-style catheter 180 includes a first proximal 184 and a second distal electrodes 182. It will be seen from this figure that the electrodes 162 and 168 of the far-field defibrillation-style catheter are relatively larger in surface area, having a total surface area of greater than about 1 cm^2 and are positioned such that there is an effective inter-electrode distance of greater than about 2 cm. By effective inter-electrode distance, the present invention contemplates the distance between two theoretical point source electrodes which would generate an electric field identical to the actual physical electrode used for the far-field electrodes. In contrast to the far-field electrodes 162 and 168 of

the defibrillation-style catheter, the electrodes 184 and 182 of the pacing-style catheter have relatively small surface areas, generally less than about 1 cm^2 and are positioned such that there is an effective inter-electrode distance of less than about 2 cm. In addition to the use of the electrodes 162 and 168 on the defibrillation-style catheter 160 as the far-field electrodes, the ICD can also use a configuration that causes the stimulation pulse current coming from the CAN electrode 152 and coming from the SUB electrode 154 to substantially to intersect the left ventricle 174, as well as the right ventricle 166. Another alternative is to use one or more epicardial patch electrodes 190 as one or more of the far-field electrodes.

Figure 7 shows schematically a circuit 200 used to produce the stimulation pulse series in an embodiment of the present invention that utilizes both far-field electrodes 202a, 202b and pacing electrodes 204a, 204b. A battery 206 is used to supply current to the primary coil 208 of transformer 210. The secondary coil 212 of the transformer 210 produces a fly-back voltage which is rectified by diode 214 and stored in capacitor 216. For delivery of conventional pacing pulses, switch 220 is enabled which delivers a battery voltage (nominal 6 volt) to the pacing electrodes 204a, 204b. If switch 222 is enabled, it delivers the high voltage present on capacitor 216 to the far-field electrodes 202a, 202b. It will be appreciated that the capacitor of the present invention can be either a single capacitor, or a combination of capacitors having an effective capacitance required to store the necessary energy for the cardioversion pulses and defibrillation countershocks. Similarly, it will also be appreciated that the voltage of the pacing pulses can be doubled using a simple voltage doubler circuitry.

CLAIMS

1. A method for operating an implantable device connected to at least two implanted electrodes located in a human patient to treat ventricular tachycardia, the method comprising the device-implemented steps of:

(a) sensing a ventricular tachycardia in the human patient; and

(b) in response to the ventricular tachycardia, delivering a series of two or more anti-tachycardia electrical stimulation pulses each having an energy value of less than about 5 joules to the two or more electrodes in a committed burst of less than about 5 seconds, at least one of the stimulation pulses being a far-field pulse having an energy value between about 0.01 joule and 5 joules, an amplitude between about 5 volts and 200 volts, and being delivered through two or more far-field electrodes having a combined surface area that exceeds about 1 square centimeter and an inter-electrode distance of greater than about 2 centimeters.

2. An implantable apparatus for treating ventricular tachycardia in a human patient, comprising:

two or more implanted electrodes, including at least a pair of far-field electrodes having a combined surface area that exceeds about 1 square centimeter and an inter-electrode distance of greater than about 2 centimeters;

means for sensing a ventricular tachycardia in the human patient; and

means for delivering a series of two or more anti-tachycardia electrical stimulation pulses in response to the ventricular tachycardia, each stimulation pulse having an energy value of less than about 5 joules to the two or more electrodes in a committed burst of less than about 5 seconds, at least one of the stimulation pulses being a far-field pulse delivered through the far-field electrodes and having an energy value between about 0.01 joule and

5 joules and an amplitude between about 5 volts and 200 volts.

3. The implantable apparatus of claim 2 wherein the means for delivering a series of stimulation pulses comprises:

capacitor means for storing a preselected amount of electrical energy for at least the far-field pulses;

high voltage charging circuit means for charging the capacitor means to the preselected amount of electrical energy;

switch means for selectively controlling a time-truncated discharge of the capacitor means through the far-field electrodes in response to the ventricular tachycardia to produce the stimulation pulses.

4. The implantable apparatus of claim 3 further comprising:

at least a pair of pacing electrodes having a combined surface area less than about 1 square centimeter and an inter-electrode distance of less than about 2 centimeters; and

power source means operably connected to said switch means for directly producing one or more pacing pulses each having an energy value of less than about 100 μjoules to be delivered through the pacing-style electrodes as part of the series of stimulation pulses.

5. The invention of claim 1 and 2 wherein the far-field pulses each have a duration of less than about 5 milliseconds.

6. The invention of claim 1 and 2 wherein more than one burst of the series of stimulation pulses are used to treat the ventricular tachycardia.

7. The invention of claim 1 and 2 wherein the total number of stimulation pulses in the burst is less than about ten.

8. The invention of claim 1 and 2 wherein the ventricular tachycardia

is sensed as a continuous sequence of intrinsic ventricular tachycardial contractions having a rate of between 150-240 bpm.

9. The invention of claim 1 and 2 wherein the far-field pulses are delivered from a capacitor which does not store electrical energy for a defibrillation countershock pulse, the capacitor having an effective capacitance of less than about 15-20 microfarads.

10. The invention of claim 1 and 2 wherein a first pulse in the series of stimulation pulses is a far-field pulse and all subsequent pulses in the series of stimulation pulses are pacing pulses delivered through two or more pacing electrodes having a combined surface area of less than about 1 square centimeter and an inter-electrode distance of less than about 2 centimeters.

11. The invention of claim 1 and 2 wherein the ventricular tachycardia is sensed as a continuous sequence of intrinsic ventricular tachycardial contractions, and wherein the first pulse is delivered at an interval following a ventricular tachycardial contraction that is shorter than an interval between sequential ventricular tachycardial contractions and the subsequent stimulation pulses are spaced from the first pulse and from each other by intervals at least as short as that between the first pulse and the preceding ventricular tachycardial contraction.

12. The invention of claim 1 and 2 wherein the ventricular tachycardia is sensed as a continuous sequence of intrinsic ventricular tachycardial contractions, and wherein a first and second pulse in the series of stimulation pulses are far-field pulses delivered at an interval following a ventricular tachycardial contraction that is shorter than the interval between ventricular tachycardial contractions, the first and second far-field pulses being separated by an interval at least as short as that between the first pulse and the preceding ventricular tachycardial contraction, and the

second pulse being followed by a short train of pacing pulses delivered through two or more pacing electrodes having a combined surface area of less than about 1 square centimeter and an inter-electrode distance of less than about 2 centimeters, the short train of pacing pulses being spaced from the first and second far-field pulses and from each other by intervals at least as short as that between the first and second far-field pulses.

13. The invention of claim 1 and 2 wherein the ventricular tachycardia is sensed as a continuous sequence of intrinsic ventricular tachycardial contractions, and wherein a first and second pulse in the series of stimulation pulses are far-field pulses delivered at an interval following a ventricular tachycardial contraction that is shorter than the interval between ventricular tachycardial contractions, the first and second far-field pulses being separated by an interval at least as short as that between the first pulse and the preceding ventricular tachycardial contraction, and the second pulse being followed by a short train of pacing pulses delivered through two or more pacing electrodes having a combined surface area of less than about 1 square centimeter and an inter-electrode distance of less than about 2 centimeters, the short train of pacing pulses being spaced from the first and second far-field pulses and from each other by intervals that are different from that between the first and second far-field pulses.

14. The invention of claim 1 and 2 wherein the ventricular tachycardia is sensed as a continuous sequence of intrinsic ventricular tachycardial contractions, and wherein a first pulse in the series of stimulation pulses is a conventional cardioversion pulse and the subsequent pulses in the series of stimulation pulses are conventional anti-tachy pacing pulses delivered without any intervening monitoring of the ventricular tachycardial contractions after an interval that is shorter than the interval between ventricular tachycardial contractions.

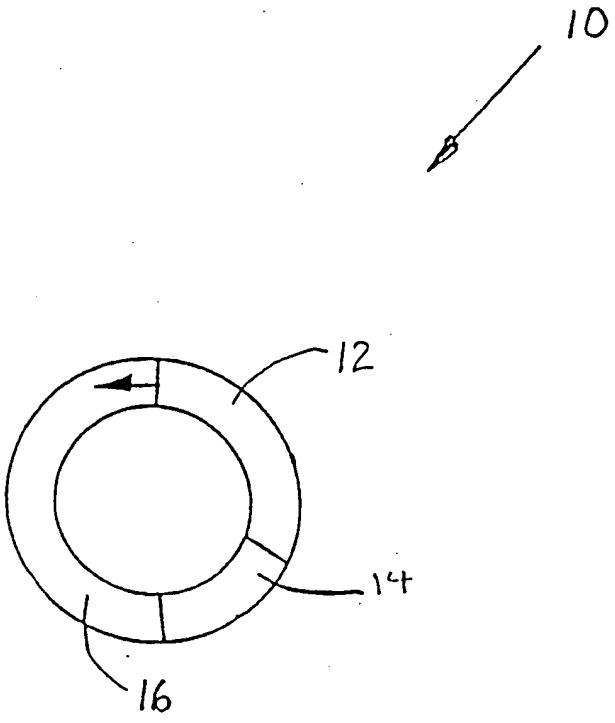


FIG. 1

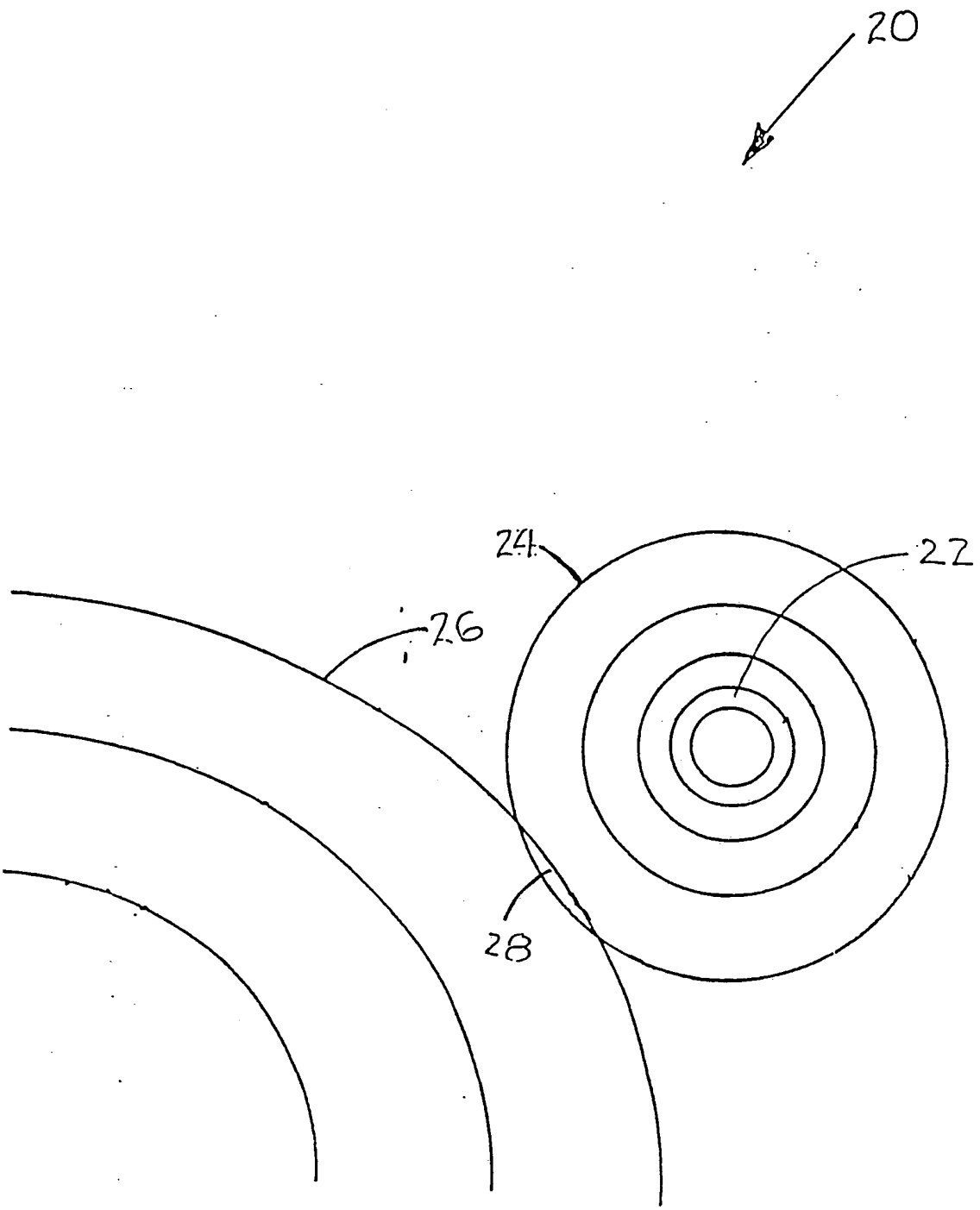


FIG. 2

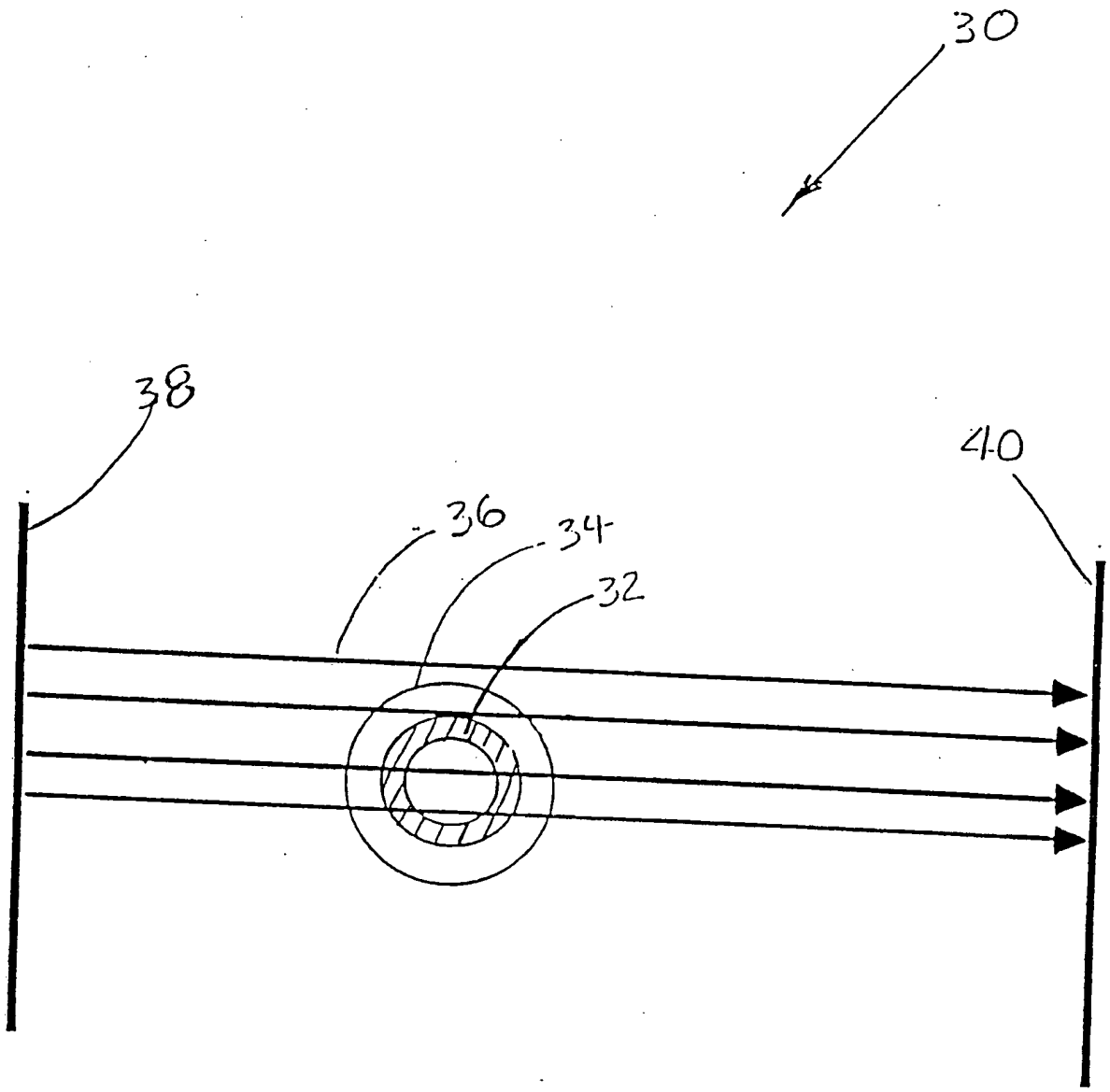


FIG. 3

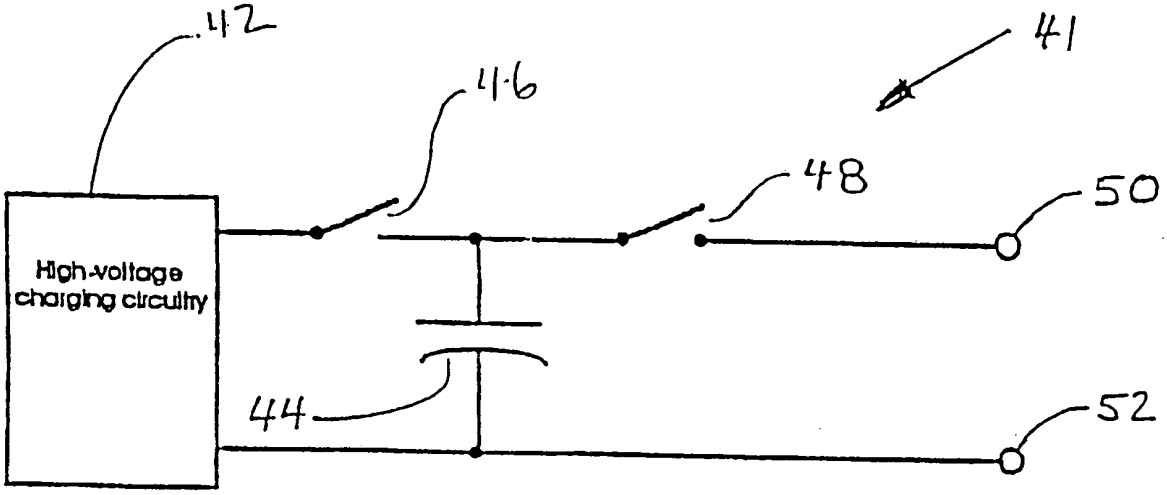


FIG. 4

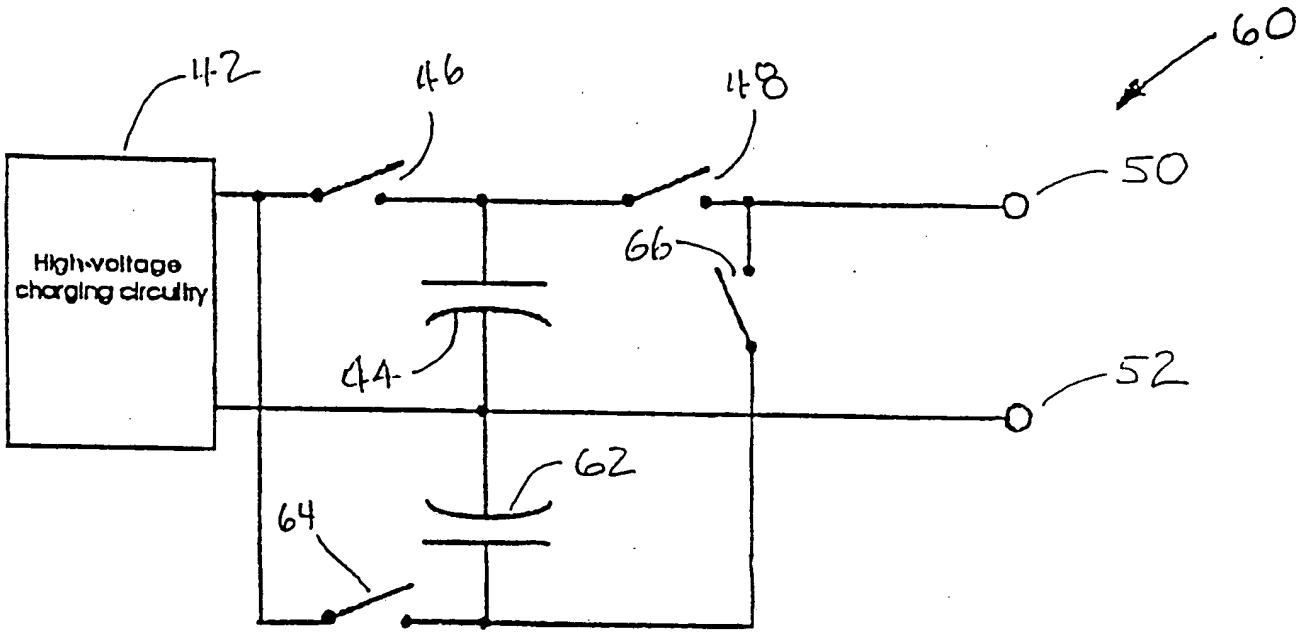


FIG. 5

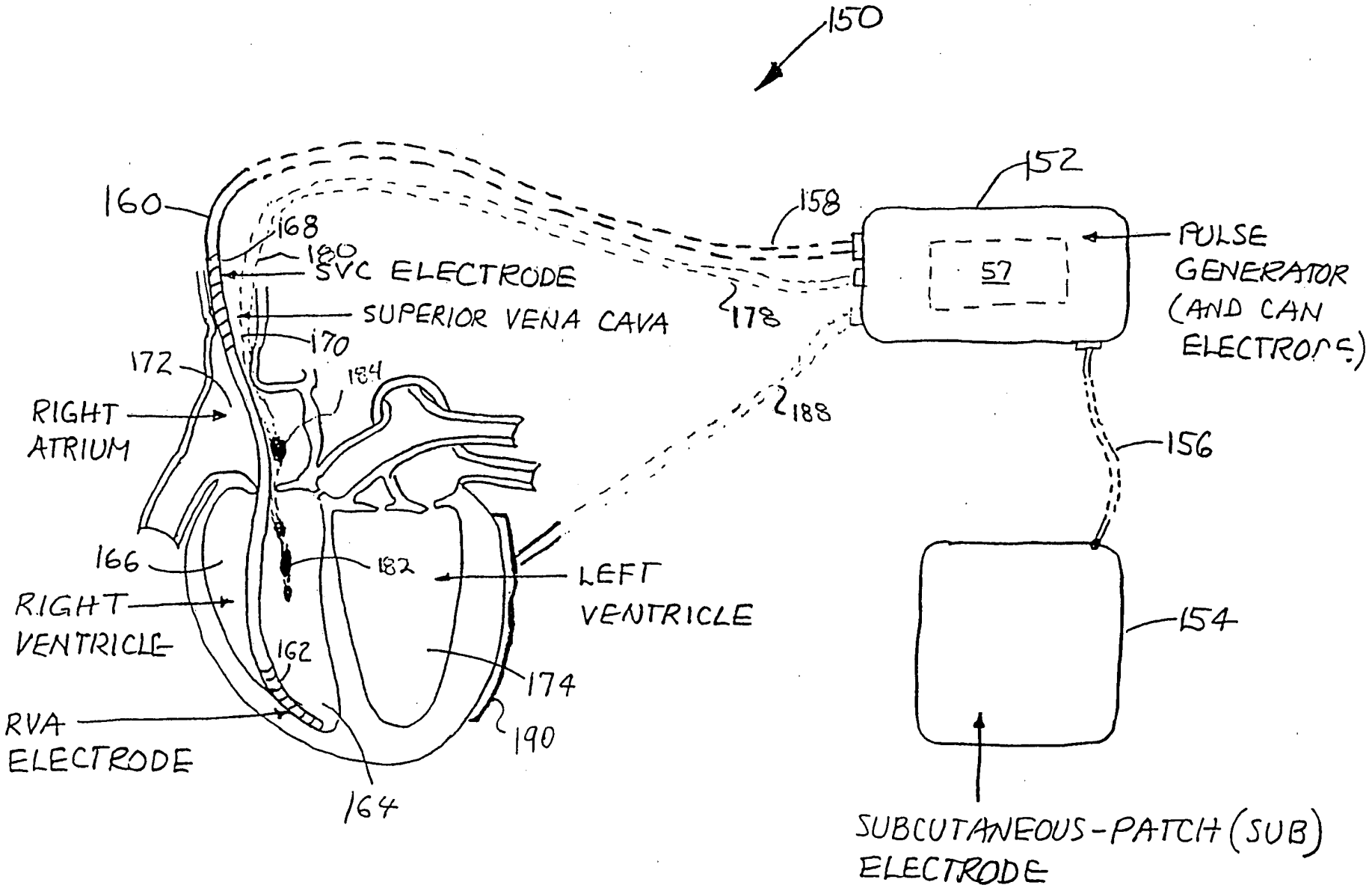
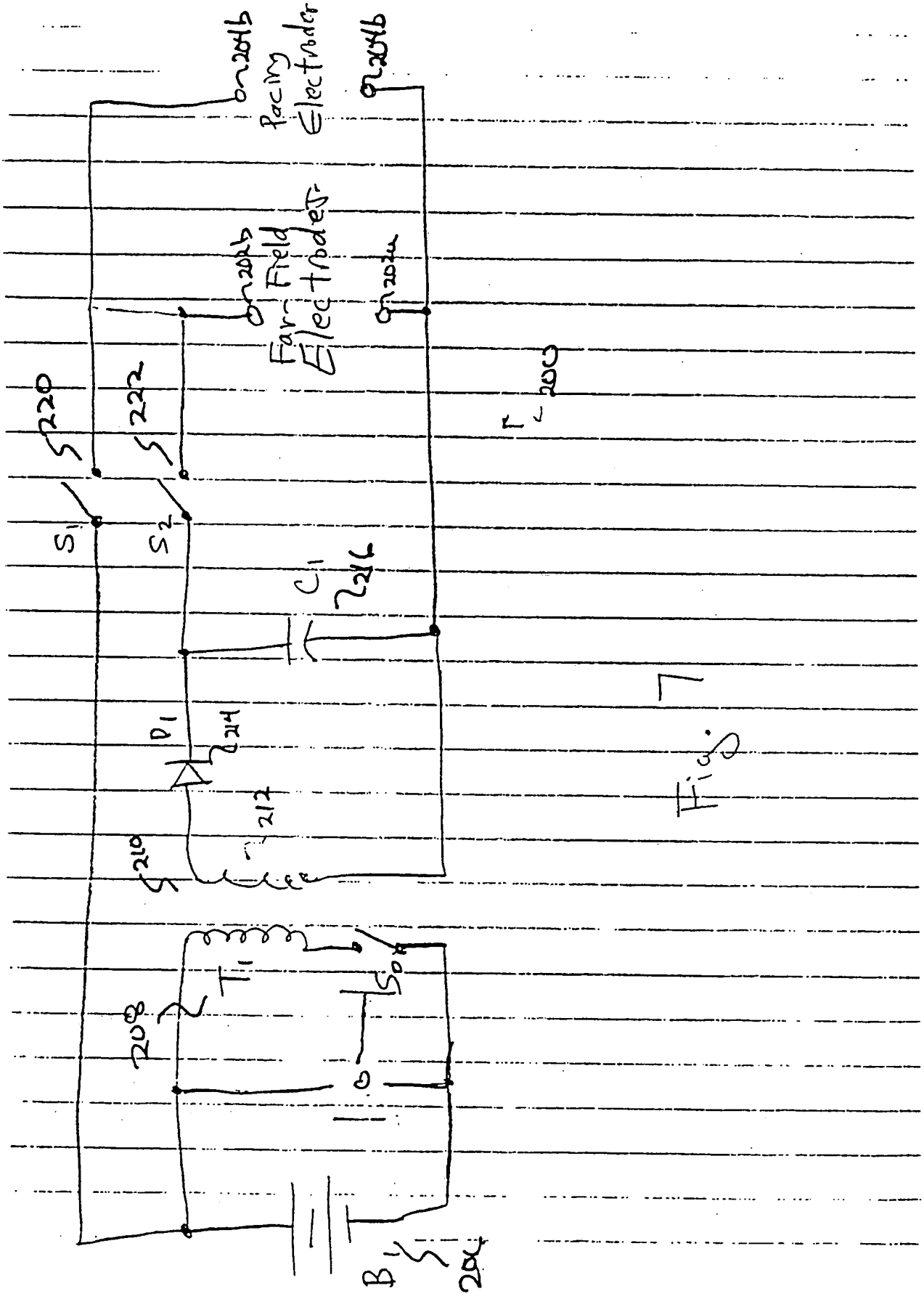

150
160
168
180
SVC ELECTRODE
SUPERIOR VENA CAVA
170
172
184
RIGHT ATRIUM
166
RIGHT VENTRICLE
162
RVA ELECTRODE
164
182
LEFT VENTRICLE
174
190
158
178
188
152
57
PULSE GENERATOR (AND CAN ELECTRODE)
156
154
SUBCUTANEOUS-PATCH (SUB) ELECTRODE

FIG. 6


Pacing Electrode
Far Field Electrode
220
222
S1
S2
C1
216
D1
214
212
210
208
T1
S0
B1
204
206
Fig. 2

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61N1/39

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61N

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
Y	US,A,4 403 614 (W. R. ENGLE ET AL.) 13 September 1983	2,3,8
A	see abstract see column 1, line 25 - line 55 see column 2, line 18 - line 42 see column 3, line 20 - line 68 see column 5, line 7 - line 20	4,6,9,10
Y	EP,A,0 095 726 (PURDUE RESEARCH FOUNDATION) 7 December 1983	2,3,8
A	see abstract see page 2, line 20 - page 3, line 10 see page 11, line 30 - page 12, line 8; figures 1-3	5

-/--

° Special categories of cited documents :[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
21 JULY 1993	12. 08. 93
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	FONTENAY P.H.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	FR,A,2 528 708 (M. MIROWSKI) 23 December 1983 see page 1, line 1 - line 8 see page 3, line 29 - page 5, line 26 see page 11, line 32 - page 14, line 1; figures	2,3,6,7, 10-14
A	MEDICAL & BIOLOGICAL ENGINEERING vol. 6, no. 3, March 1968, (GB) pages 167 - 169 J. E. W. KUGELBERG 'ventricular defibrillation with double square pulse' * see sections 1-4, page 167 *	6,7, 11-14

INTERNATIONAL SEARCH REPORT

PCT/US 93/03267

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1 (iv) methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods,

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

US 9303267
SA 72796

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 21/07/93

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-4403614	13-09-83	AU-B-	538816	30-08-84
		AU-A-	6066680	22-01-81
		CA-A-	1160296	10-01-84
		EP-A,B	0023134	28-01-81
EP-A-0095726	07-12-83	DE-A-	3378355	08-12-88
		US-A-	4548203	22-10-85
		US-A-	4708145	24-11-87
FR-A-2528708	23-12-83	US-A-	4559946	24-12-85
		AU-B-	558515	29-01-87
		AU-A-	1574383	22-12-83
		CA-A-	1210819	02-09-86
		DE-A,C	3321695	05-01-84
		GB-A,B	2122093	11-01-84
		JP-C-	1405397	09-10-87
		JP-A-	59057669	03-04-84
		JP-B-	62015234	06-04-87
		NL-A-	8302182	16-01-84